

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants : Hanson S. Gifford III Confirmation No.: 2779
Serial No. : 10/790,540 Art Unit : 3733
Filed : March 1, 2004 Examiner : D.C. Comstock
Title : A Device for Engaging Tissue Having a Preexisting Opening

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1.6(a)(4) on September 15, 2008

/Brian S. Tomko/

Brian S. Tomko

(Name of applicant, assignee, or Registered Representative)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notification of Non-Compliant Appeal Brief dated September 29, 2008, and the Notice of Appeal, which was mailed by Applicant to the U.S. Patent & Trademark Office on March 14, 2008, the time for filing having been extended by petition. Applicant has modified the Appeal Brief to respond to the issues raised in the Notification.

Real Party In Interest:

The real party in interest for this patent application is Heartport, Inc., Somerville, NJ, USA.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellants, the Appellants' legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 1-20 are cancelled. Claims 21-47 are pending. Claims 21-47 have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of February 5, 2008.

Summary of Claimed Subject Matter:

The subject matter claimed in independent claim 21 is a device for engaging tissue having a preexisting opening that includes a generally annular-shaped ring, at least two staple members that extend from the ring having at least a distal portion formed of an elastic material, the distal portions having a first configuration, and a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring. One embodiment of the claimed device is described generally at paragraphs 0190-0191 of U.S. Application Publication No. 2004/0167551, and is depicted at Figures 38A-38C (page 80, line 4 through page 81, line 15 of the original specification).

Referring to Figures 38A-38C, the claimed device 481 includes a generally annular-shaped ring 482 defining a plane, the ring being disposed about a central axis extending through the plane, at least two staple members 483 extending from the ring, and a member 485 configured to be disposed within the ring. Each of the staple members has at least a distal

portion (e.g., reference numeral 490) that is formed of an elastic material. The distal portions have a first configuration, depicted in Figure 38B, where the distal portions 490 are separated by a first distance, and wherein the distal portions 490 are substantially parallel to the central axis, and a second configuration, depicted in Figures 38A or 38C, where the distal portions 490 are separated by a second distance, the second distance being less than the first distance. The member 485 is configured to bias the distal portions 490 of the staple members to the first configuration when the member 485 is disposed within the ring 482.

The subject matter claimed in independent claim 39 is a device 481 for engaging tissue having a preexisting opening that includes a ring 482 having at least two staple members 483 that extend therefrom and a member 485 configured to be disposed within the ring 482. One embodiment of the claimed device is described generally at paragraphs 0190-0191 of U.S. Application Publication No. 2004/0167551, and is depicted at Figures 38A-38C (page 80, line 4 through page 81, line 15 of the original specification).

The staple members 483 each have a distal end 490. The device 481 has a first configuration, depicted in Figure 38B, where the member 485 is disposed within ring 482, and a second configuration, depicted in Figures 38A or 38C, where member 485 is not disposed within ring 482, and wherein the distal ends 490 of the staple members 483 are substantially parallel to the central axis when the device is in the first configuration, and the distal ends 490 of the staple members 483 are substantially orthogonal to the central axis when the device is in the second configuration.

Grounds of Rejection to be Reviewed on Appeal:

A) Whether the final rejection stating that claims 21-37 and 39-46 are anticipated under 35 U.S.C. 102(e) by U.S. Patent No. 5,478,354 (Tovey) should be reversed.

B) Whether the final rejection stating that claims 38 and 47 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,478,354 (Tovey) should be reversed.

Argument:

A) Whether the final rejection stating that claims 21-37 and 39-46 are anticipated under 35 U.S.C. 102(e) by U.S. Patent No. 5,478,354 (Tovey) should be reversed.

Appellants submit that the claimed invention is novel (and not obvious with respect to claims 38 and 47) in view of Tovey as Tovey does not set forth each and every element of the claims.

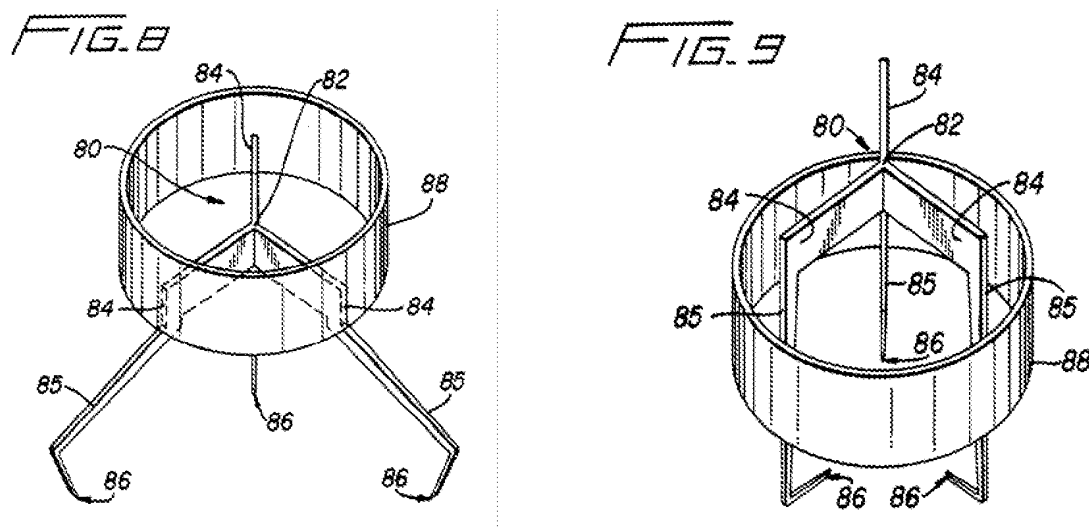
Independent claim 21

Claim 21, as amended, requires, among other elements, a ***generally annular-shaped ring*** defining a plane, the ring being disposed about a central axis extending through the plane; at least two staple members extending from the ring, each of the at least two staple members having at least a distal portion formed of an elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and ***wherein the distal portions are substantially parallel to the central axis***, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance; and a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring.

The Examiner references two embodiments of Tovey relative to the claimed invention. The first is depicted at Figures 8 and 9 and is described at column 4, lines 32-44 of the specification. The second embodiment of Tovey is depicted at Figures 10 and 11 and is described at column 4, line 44 to column 5, line 19 of the specification. These two embodiments are described separately in Tovey; they do not function together. As a result, Appellants analyze each separately.

The First Tovey Embodiment

The first Tovey embodiment, depicted in Figures 8 and 9, is described as a surgical fastener comprising a Y-shaped base 82 having leg portions 84 integral therewith. As moveable collar 88 is moved over the Y-shaped base 82 it moves leg portions 84 from a first position, shown in Figure 8, to a second position, shown in Figure 9.



The first Tovey embodiment does not teach or suggest the invention of claim 21. As discussed above, claim 21 requires a generally annular-shaped ring and at least two staple members that extend from the ring. The first Tovey embodiment does not teach or suggest a ring having at least two staple members extending from the ring. The device of the first Tovey embodiment is a Y-shaped fastener 82 having legs 84 extending therefrom. Element 88, described as a moveable collar, the only element that resembles a the claimed ring element, does not have staple members extending from it.

Further, the first Tovey embodiment does not teach or suggest the last element of claim 21--a member configured to bias the distal portions of the at least two staple members to the first configuration *when the member is disposed within the ring*. Tovey does not describe the requisite ring, and therefore can not describe a member that is disposed within the ring. Instead,

Tovey depicts a y-shaped device having legs 85 that is biasable from a first open configuration, depicted in Figure 8, to a second closed configuration, depicted in Figure 9. The collar 88 is disposed about the y-shaped device 82.

Claims 22-38 that depend from claim 21 are also allowable over this first Tovey embodiment as they depend from claim 21 and for other reasons that will be omitted for brevity's sake.

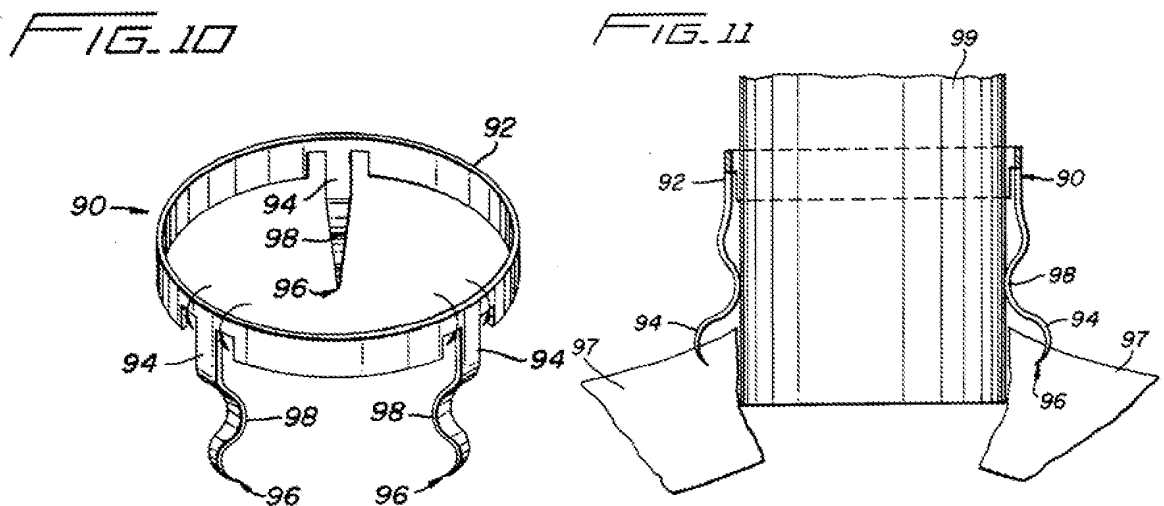
Independent claim 39

For similar reasons, Appellants submit that the first Tovey embodiment does not teach or suggest the elements of claim 39. Claim 39 claims a system that includes a device comprising: a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and a member configured to be disposed within the ring; and wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration.

As described above with respect to claim 21, the first Tovey embodiment does not teach or suggest a ring or a member configured to be disposed within the ring. As such, Appellants submit that claim 39 and those claims that depend from claim 39 are allowable.

The Second Tovey EmbodimentIndependent claim 21

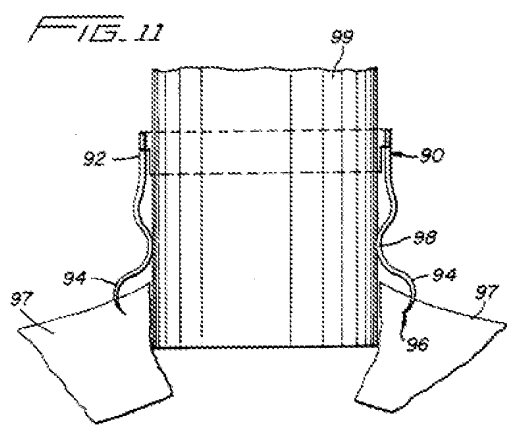
The Examiner also suggested that the second embodiment of Tovey anticipates the claimed invention. The second embodiment is depicted at Figures 10 and 11 and is described at column 4, line 44 to column 5, line 19 of the specification.



The second Tovey embodiment does not teach or suggest the invention claimed in claim 21. As discussed above, the device of claim 21, requires, among other elements, a generally annular-shaped ring defining a plane, the ring being disposed about a central axis extending through the plane; at least two staple members extending from the ring, each of the at least two staple members having at least a distal portion formed of an elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and ***wherein the distal portions are substantially parallel to the central axis***, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance; and a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring.

In particular, Tovey does not teach or suggest that the distal portions of the at least two staple members are substantially parallel to the central axis of the ring when the at least two staple members are in the first configuration; i.e., when the member is disposed within the ring. The second Tovey embodiment depicts a fastener configured to fit outside a cannula. The fastener has legs 94 that extend from a bottom surface of a base 92. The legs 92 have camming surfaces 98 that abut the cannula when the cannula resides within the base.

In contrast to the invention claimed in claim 21, Tovey's legs 94 are not "substantially parallel to the central axis of the ring". Instead, following the profile of legs 94 away from base 92, legs 94 undulate away from the central axis, then toward the central axis to form cam surface 98, and then back away from the central axis, before ending in a barb 96 that points toward the central axis. As a result, legs 94 can not be considered to be substantially parallel to the central axis of the ring.



Dependent Claims 24, 37 and 38

Further, with respect to the dependent claims, the second Tovey embodiment also does not teach or suggest the elements of at least claims 24, 37 and 38. Claim 24 depends from claim 21 and further requires that the distal portion of the at least two staple members are

substantially orthogonal to the central axis when the distal portions are in the second configuration. Reviewing Figure 10 of Tovey, barbs 96 are not substantially orthogonal to the central axis when the cannula 99 is not disposed within base 92.

Claim 37 also depends from claim 21, and further requires that the ring has an inner periphery and the at least two staple members member extend from the inner periphery. The legs 94 of Tovey extend from the bottom surface of base 92, as is shown in Figures 10 and 11. As a result, Tovey does not teach the elements of claims 37.

Dependent Claims 39-46

Further, the second Tovey embodiment does not anticipate claim 39 or its dependents for reasons similar to those described above. Claim 39 claims a system for engaging tissue having a preexisting opening that includes: a device comprising a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and a member configured to be disposed within the ring; and wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration. Tovey does not teach or suggest that the distal ends are substantially parallel to the central axis when the device is in the first configuration. Nor does Tovey teach or suggest that distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration. Claim 46 is allowable for reasons similar to those discussed with respect to claim 37 above.

B) Whether the final rejection stating that claims 38 and 47 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,478,354 (Tovey) should be reversed.

Appellants submit that claims 38 and 47 are allowable over U.S. Patent No. 5,478,354 (Tovey). Claim 38 depends from claim 37 and further requires that the at least two staple members comprise at least four staple members, and each of the at least four staple members extend from the inner periphery at positions that are angularly offset with respect to one another by substantially the same angle. The legs 94 of Tovey extend from the bottom surface of base 92, as is shown in Figures 10 and 11, not from the periphery. As a result, Tovey does not suggest the elements of claim 38. Claim 47 is allowable for reasons similar to those discussed with respect to claim 38 above.

Conclusion:

As such, for the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 21-47 as being unpatentable should be reversed.

Respectfully submitted,

By: /Brian S. Tomko/
Brian S. Tomko
Reg. No. 41,349

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2823
Dated: October 29, 2008

APPENDIX

1-20. (Cancelled)

21. (Previously Presented) A device for engaging tissue having a preexisting opening, comprising:

a generally annular-shaped ring defining a plane, the ring being disposed about a central axis extending through the plane;

at least two staple members extending from the ring, each of the at least two staple members having at least a distal portion formed of an elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and wherein the distal portions are substantially parallel to the central axis, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance; and

a member configured to be disposed within the ring, the member configured to bias the distal portions of the at least two staple members to the first configuration when the member is disposed within the ring.

22. (Previously Presented) The device of claim 21, wherein the first distance is greater than the diameter of the preexisting opening.

23. (Previously Presented) The device of claim 21, wherein the second distance is less than the diameter of the preexisting opening.

24. (Previously Presented) The device of claim 21, wherein the distal portion of the at least two staple members are substantially orthogonal to the central axis when the distal portions are in the second configuration.

25. (Previously Presented) The device of claim 21, wherein the distal portions end in a sharpened point.

26. (Previously Presented) The device of claim 21, wherein the distal portions are located radially inward relative to the annular ring when the distal portions are in the second configuration.

27. (Previously Presented) The device of claim 21, wherein the distal portions of the at least two staple members are not parallel with the central axis when the distal portions are in the second configuration.

28. (Previously Presented) The device of claim 21, wherein the member has a longitudinal axis that is parallel to the central axis.

29. (Previously Presented) The device of claim 28, wherein the member is a tubular member.

30. (Previously Presented) The device of claim 21, wherein the member is slidable within the ring.

31. (Previously Presented) The device of claim 21, comprising a driver disposed about the member.

32. (Previously Presented) The device of claim 31, wherein the driver and the member are movable with respect to one another.

33. (Previously Presented) The device of claim 32, wherein the driver is configured to move the ring from a first position relative to the member to a second position relative to the member, whereat the at least two staple members engage tissue.

34. (Previously Presented) The device of claim 21, wherein the distal portions of the staple members are formed of a superelastic material.

35. (Previously Presented) The device of claim 21, wherein the distal portions of the staple

members are formed of a shape-memory material.

36. (Previously Presented) The device of claim 21, wherein the staple members are integrally formed with the ring.

37. (Previously Presented) The device of claim 21, wherein the ring has an inner periphery and the at least two staple members extend from the inner periphery.

38. (Previously Presented) The device of claim 37, wherein the at least two staple members comprise at least four staple members, and each of the at least four staple members extend from the inner periphery at positions that are angularly offset with respect to one another by substantially the same angle.

39. (Previously Presented) A system for engaging tissue having a preexisting opening, comprising:

- a device comprising a ring disposed about a central axis and at least two staple members extending therefrom, the at least two staple members each having a distal end; and
- a member configured to be disposed within the ring; and

- wherein the device has a first configuration, where the member is disposed within the ring, and a second configuration, where the member is not disposed within the ring, and wherein the distal ends of the at least two staple members are substantially parallel to the central axis when the device is in the first configuration, and the distal ends of the at least two staple members are substantially orthogonal to the central axis when the device is in the second configuration.

40. (Previously Presented) The device of claim 39, wherein the ring is generally annular in shape.

41. (Previously Presented) The device of claim 39, wherein the ring and staple members are formed of a superelastic material.

42. (Previously Presented) The device of claim 39, wherein the member is moveable along the central axis relative to the ring.

43. (Previously Presented) The device of claim 39, comprising a driver disposed about the member.

44. (Previously Presented) The device of claim 39, wherein the driver and the member are movable with respect to one another.

45. (Previously Presented) The device of claim 44, wherein the driver is configured to move the ring from a first position relative to the member to a second position relative to the member, whereat the at least two staple members engage tissue.

46. (Previously Presented) The device of claim 39, wherein the ring has an inner periphery and the at least two staple members extend from the inner periphery.

47. (Previously Presented) The device of claim 46, wherein the at least two staple members comprise at least four staple members, and each of the at least four staple members extend from the inner periphery at positions that are angularly offset with respect to one another by substantially the same angle.

EVIDENCE APPENDIX

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ **1.130**, **1.131**, or **1.132** during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

RELATED PROCEEDINGS APPENDIX

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.